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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,310	08/31/1999	KOJI UKAI	425-736P	2449

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/380,310	UKAI ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-11,13-18,20-23,25,26,28-30 and 33-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11,13-18,20-23,25,26,28-30 and 33-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/07/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendments and response filed 04/20/05 and an IDS filed on 03/07/05. Claims 2, 3, 9, 10, 16, 17, 22, 25, 28, 29, 30, 37, 38 and 42 have been amended and claims 44-63 have been newly added. Accordingly claims 1-4, 6-11, 13-18, 20-23, 25-26, 28-30 and 33-63 are pending.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7-10, 14-17, 21 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Drug Information for Vantin®.

Drug information for Vantin® discloses that cefpodoxim is an antibiotic (which meets the limitation of a basic medicine) available in powder for suspension or tablet form. The active agent is mixed with other agents including carrageenan (which meets the limitation of an acidic polysaccharide), maltodextrin, natural and artificial flavoring, etc.

Claims 1,15, 20-21, 41, 43-44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsau et al (5,286,489).

Tsau discloses a drug-polymer matrix composition comprising an active agent having an amine or amido group and a pharmaceutically acceptable copolymer. The type of interaction between active agent and the copolymer depends on the chemical structure of the active agent and copolymer. Typical interactions include hydrogen bonding, salt formation ion pair, complex formation, etc (col. 3, lines 5-33). The compositions are prepared by mixing one or more active agents with an anionic copolymer or mixture of anionic copolymers in the presence of a solvent such as alcohol, acetone, ketones, etc (col. 3, lines 34-55).

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,15, 20-21, 41, 43-44 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Diehl (5,612,026).

Diehl discloses drink mix compositions comprising a therapeutically effective dose of an anionic exchange resin, from about 0.05 to about 1.25g of xanthan gum and an edible, water soluble salt (col. 2, lines 13-17). The anion exchange resin means any resinous material having cationic moieties, such as *cholestyramine* and *colestipol* hydrochloride, both of which are strongly basic anion exchange resins (col. 3, lines 15-30). Diehl also discloses that edible water soluble salts MAY be added (col. 3, lines 48-62). Other materials including bulking agents and carriers may be added. Such materials can be oligosaccharides and polysaccharides (col. 5, lines 20-45).

Diehl also discloses a method of preparing the said formulations, where cholestyramine, xanthan gum and maltodextrin are charged and allowed to mix (col. 6, lines 45-67).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-11, 13-18, 20-23, 25-26, 28-30 and 33-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diehl (5,612,026) in view of Drug information for Vantin® (PDR- 1995).

Diehl, discussed above, lacks specific disclosure on other basic medicines for the said formulation.

Drug information for Vantin® discloses that cefpodoxim is an antibiotic available in powder for suspension or tablet form. The active agent is mixed with other agents including natural and artificial flavoring, maltodextrin, carrageenan, etc.

Diehl teaches the benefit of mixing an anion exchange resin with an acidic polysaccharide to mask the unpleasant taste, and Drug information for Vantin® teaches the need for masking bitter taste of antibiotics such as cefpodoxim (by adding flavors and coating). Thus it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted one basic active agent for the other

in order to benefit from the masking properties for more medications with unpleasant taste. Furthermore, one of ordinary skill would be motivated to look for other suitable medicinal components with unpleasant taste and to implement the same method for them in order to provide the same benefit for more patients.

Claims 1-4, 6-11, 13-18, 20-23, 25-26, 28-30 and 33-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tai (5,013,557).

Tai discloses taste masking compositions comprising spray dried microcapsules containing sucralfate and methods for preparing same. The spray dried spheroidal microcapsules comprise in percentages by weight between 1 and 70% of sucralfate and between 30 and 99% of a polymer soluble in gastric fluids (col. 5, lines 30-60). The polymers soluble in the gastric fluids are polymers which bind to sucralfate with taste masking properties and dissolve in gastric fluid. The suitable polymers include alginic acid, carrageenan, xanthan, etc (col. 6, lines 26-55).

Although Tai does not exemplify compositions containing a basic medicine and an acidic polysaccharide, it does teach mixing a medicine with unpleasant taste with a polysaccharide such as carrageenan to mask the taste and thus one or ordinary skill in the art would be motivated to apply the same method to other medications with unpleasant taste in order to provide better tasting medication for patients and increase patient compliance.

Response to Arguments

Applicant's arguments filed on 04/20/05 have been fully considered but they are not persuasive.

With regard to Drug Information for Vantin®, Applicant argues that the use of carageenan is in the oral suspension and not in a tablet. Applicant also states that "the drug Information reference further fails to disclose a tablet containing carrageenan". It is noted that the claims are given their broadest reasonable interpretation. Instant claims are drawn to a "medicine composition". Certain dependent claims recite the dosage form to be one of granule, a fine granule, a powder or a tablet. Thus it is stated that the disclosed dosage form of Vantin® in the form of powder fully meets the limitations of claims. Applicant also argues that Drug Information does not recite mixing of the ingredients and does not recite the electrical interactions. This is not persuasive because 1) claim 8 recites "blending" and clearly in order to prepare a uniform powder formulation comprising two or more ingredients, they have to be blended together, thus inherently met. 2) The elèctrical interaction is also an inherent property of a **basic** medicament and an **acidic** excipient.

With regard to Diehl reference, Applicant argues that Diehl does not teach electrical interaction and also by deleting xanthan gum, Diehl is no longer a prior art. However this is not all persuasive. Electric interaction, as mentioned above, is an inherent property of an acidic and basic combination. Furthermore, claims with broader scope, specifically those that generally recited "an acidic polysaccharide" are still met by Diehl reference.

Applicant argues that "no technical evidence has been cited or provided in the Office Action to show that the skilled artisan would stray away from the objective of Diehl directed to reducing serum cholesterol level, or that the basic medicine in Diehl should or could be appropriately replaced....". Applicant continues that the two cited references are not in analogous fields. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Diehl is attempting to make the basic medicines more tolerable for patients. Meaning taste alteration or masking taste of the basic medicaments. Drug Information also discloses excipients which allow a basic medicament be more acceptable to patients. Substituting one unpleasant tasting medicament with another is clearly obvious to one of ordinary skill in the art.

With regard to Tai reference, Applicant refers to the Office Action and states that "Tai fails to exemplify compositions containing a basic medicine and an acidic polysaccharide, Applicants submit that this is the instantly claimed composition and that this is a significant deficiency of the Tai reference". Applicant's attention is drawn to the language used in the Office Action, which is "exemplify". The reasoning stated in the Office Action implied that though Tai reference is not combined with any other

references, it is used in a U.S.C. 35, 103(a) rejection. Thus the obviousness statement read that while Tai does not **exemplify** the said combination (otherwise it would have qualified for a 102 rejection), it recites all the limitations of the instant claims. The said statement should not be interpreted as Tai lacking the active agent and the polysaccharide of the instant claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Mina Haghighatian
July 22, 2005